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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,448	01/04/2001	Susan I. Shelso	06530.0275	3427

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EXAMINER	
LANDREM, KAMRIN R	
ART UNIT	**PAPER NUMBER**
3738	16

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/753,448	SHELSO, SUSAN I.	
	Examiner	Art Unit	
	Kamrin R. Landrem	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on V22/04

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-44 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the newly added limitations of a loading funnel capable of receiving the stent therein and method limitations wherein the stent is loaded onto the delivery system through the funnel must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 9-11, 13, 15, 16, 29, 30, 32, 33 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ravenscroft (USPN 5,702,418).

With reference to Figure 1, Ravenscroft discloses a delivery system 10 comprising a catheter 11 having self-expanding (10:49) stent 20 disposed on distal end near loading funnel 13. Figure 1 shows that loading funnel 13 is used to compress stent 20 on the distal end of catheter 11 within an outer member 24 during delivery into the patient's body. The catheter 11 further

comprises a guidewire 31 and a tubular member 17 comprising at least three radiopaque marker bands 37 that indicate the leading, middle, and trailing ends of stent 20. Figure 5 discloses 4 dark rings indicating four marker bands with the first band being located near the distal end 50 of the stent to indicate the end that is leading into the vessel and the portion of the stent that will be expanded first. The catheter also has an outer member 24 that is slidable relative to the tubular member (5:15-22) and is configured to retain the stent 20 in a radially compressed position. In one embodiment Ravenscroft discloses an inflatable balloon device 60 disposed on the catheter beneath the stent (7:10-13). The marker bands can be used to indicate a position corresponding to the re-constrain limit of a partially deployed stent (7:53-59). Ravenscroft also discloses the method for implanting a self-expanding stent comprising the following steps; providing the stent/deployment system combination, delivering the system to the target region, partially deploying the stent, re-constraining the stent, and inflating the balloon device to assist the expansion of the stent (6:21-58 and 7:1-41).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the s subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5, 6, 17-21, 23, 24, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft in view of Lenker et al (USPN 5,749,921).

Ravenscroft, as discussed above, discloses the stent delivery device as claimed. Ravenscroft however fails to teach the loading the stent onto the delivery system through the delivery funnel. Lenker teaches a the device and method of loading a stent 72 into a delivery catheter prior to deployment by attaching removable cartridge 102 comprising flared portion 100 thereby allowing the stent to be loaded in the operating room prior to deployment to avoid shipping and storing the prosthesis in a compressed configuration (7:1-25). After the stent 72 is loaded within sheath 106 it is detached from the delivery system and disposed at the end of a delivery catheter. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the delivery device disclosed by Ravenscroft in order to incorporate the method of loading the stent as taught by Lenker in order avoid storing the stent in a compressed configuration thereby promoting resilient expansion of the stent to its full diameter when it is released.

Claim 31,36-39,41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over St. Germain (USPN 5,534,007) in view of Lenker et al (USPN 5,749,921).

St. Germain et al discloses a delivery system 5 for a self-expanding stent comprising a catheter 5 having a tubular member with an inflatable balloon disposed beneath a self-expandable stent 35 and a loading funnel 25 disposed on its distal end. The catheter also includes a holding sleeve 60 and an outer member 40 that is slidable relative to the tubular member (3:26-59). The loading funnel is capable of assisting with compression of the stent by fixing it in place in the axial direction. The tubular member defines a first lumen 15 for guidewire 20 and second lumen for providing a fluid passage (3:57-59). St. Germain discloses the combination of the stent and delivery system as claimed. St. Germain however fails to disclose that the stent is capable of

being received within the loading funnel. Lenker teaches a the device and method of loading a stent 72 into a delivery catheter prior to deployment by attaching removable cartridge 102 comprising flared loading portion 100 thereby allowing the stent to be loaded in the operating room prior to deployment to avoid shipping and storing the prosthesis in a compressed configuration (7:1-25). After the stent 72 is loaded within sheath 106 it is detached from the delivery system and disposed at the end of a delivery catheter. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the delivery device disclosed by St. Germain in order to incorporate the method of loading the stent as taught by Lenker in order avoid storing the stent in a compressed configuration thereby promoting resilient expansion of the stent to its full diameter when it is released.

Claims 8,12,14,22,25,26,27, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft as modified by Lenker, further in view of St. Germain et al.

Ravenscroft, as discussed above, discloses the stent delivery device and method for implantation of a self-expanding stent as claimed. Ravenscroft however fails to teach the inflation means for the inflatable balloon device 60 disposed on the catheter beneath the stent (7:10-13) and a holding sleeve configured to hold the self-expanding stent. St. Germain teaches a stent delivery device comprising a catheter 5 having a tubular member with an inflatable balloon disposed beneath a self-expandable stent 35 a first lumen 15 for guidewire 20 and second lumen for providing a fluid passage (3:57-59), and a holding sleeve 60 for maintaining the position of the compressed stent. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the delivery system

of Ravenscroft with the inflation means and holding sleeve as disclosed by St. Germain in order to inflate the balloon and to maintain appropriate stent positioning within the catheter.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over St. Germain in view of Ravenscroft.

St. Germain et al discloses a delivery system 5 for a self-expanding stent comprising a catheter 5 having a tubular member with an inflatable balloon disposed beneath a self-expandable stent 35 and a loading funnel 25 disposed on its distal end. The catheter also includes a holding sleeve 60 and an outer member 40 that is slidable relative to the tubular member (3:26-59). The loading funnel is capable of assisting with compression of the stent by fixing it in place in the axial direction. The tubular member defines a first lumen 15 for guidewire 20 and second lumen for providing a fluid passage (3:57-59). St. Germain as discussed, discloses the delivery system as claimed however St. Germain fails to disclose three marker bands and their locations relative to the stent. Ravenscroft discloses a catheter 11 further comprises a guidewire 31 and a tubular member 17 comprising at least three radiopaque marker bands 37 that indicate the leading, middle, and trailing ends of stent 20 that ensure proper positioning of the stent within the patient (6:21-58 and 7:1-41). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the delivery system as disclosed by St. Germain by incorporating the three marker bands as taught by Ravenscroft to enable to appropriately position the stent within the patient's vessel.

Response to Arguments

Applicant's arguments filed January 22, 2004 have been fully considered but they are not persuasive. With regards to applicant's arguments concerning the placement of three marker bands, Ravenscroft does disclose at least three marker bands, which can be used to indicate to the surgeon the leading, middle and trailing locations of the stent during implantation. With regards to applicant's arguments concerning the loading funnel being capable of holding a stent therein, the drawings do not show this feature. The drawings have been objected to for failing to show that the funnel is capable of passing the stent therethrough. Lenker is used as a teaching reference to meet the newly added limitations of compressing the stent and passing it through the loading funnel prior to deployment.

Applicant's arguments with respect to independent claims 5, 17, 31, and 36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kamrin Landrem
Examiner
AU 3738

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